MAR 2 8 2014

K131939

510(k) SUMMARY
(as required by 807.92)

Regulatory Correspondent:	AJW Technology Consultants, Inc 445 Apollo Beach Blvd Apollo Beach, FL 33572 Lauren Chrapowitzky laurenc@ajwtech.com 813-645-2855 813-645-2856
Submitter of 510(k):	Amico Diagnostic Incorporated 55 East Wilmot St. Richmond Hill, ON L4B 1A3 CANADA Eric Charron echarron@amico.com
Date of Summary:	30 August 2013
Trade/Proprietary Name:	Amico DH-W35 Ophthalmoscope Series
Common/Usual Name:	Ophthalmoscope, Ac-Powered
Classification Name:	Ophthalmoscope
Product Code:	HLI
Indications for Use:	An ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye.
Device Description:	The ophthalmoscope is an AC powered hand-held device containing illumination and viewing optics to examine the cornea, aqueous, lens, vitreous, and the retina of the eye.
Predicate Device:	K950461 – Welch Allyn Ophthalmoscope
Substantial Equivalence:	The applicant device has the same fundamental technological characteristics as the predicate device. Performance testing between the predicate device and the subject device have verified substantial equivalence in design, materials and intended use,

	and confirmed there are no significant differences between the proposed and predicate devices that raise new questions of safety or efficacy. A comparison chart has been included in Section 12 of this submission.
Performance Testing:	The FDA Ophthalmoscope Guidance Document [Ophthalmoscope Guidance (Direct and Indirect) Version 1.0, July 8. 1998] was utilized to determine performance testing requirements. Performance testing was completed per ISO 10942 and ISO 15004-2 requirements. Additionally, electrical safety testing was performed per IEC 60601-1 and UL60601-1-2. Results of these tests (included in Sections 17 and 18 of the submission) demonstrate that the Amico Ophthalmoscope is as safe as or safer than the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 26, 2014

Amico Diagnostics Incorporated
% Ms. Lauren Chrapowitzky
Regulatory Consultant
AJW Technology Consultants, Inc.
445 Apollo Beach Blvd.
Apollo Beach, FL 33572

Re: K131939
Trade/Device Name: Amico DH-W35 Ophthalmoscope Series (Models DH-W35 and DH- W35-CH-L)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: February 6, 2014
Received: February 10, 2014

Dear Ms. Chrapowitzky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131939

Device Name
Amico DH-W35 Ophthalmoscope Series

Indications for Use *(Describe)*

An ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous and retina of the eye.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Marsha L. Burke Nicholas -S

Digitally signed by Marsha L. Burke Nicholas -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300014022, cn=Marsha L. Burke Nicholas -S
Date: 2014.03.25 12:31:33 -04'00'